REMARKS

Claims 26-34, 37-38, 53-61, and 79 are pending in the present application. Claims 26, 37, 53, 60, and 79 have been amended to more particularly point out and distinctly claim the invention. No new matter is added by these amendments.

The Rejection Under 35 U.S.C. § 103(b)

Claims 26, 30, 33, 37, 53, 56, 58-60 and 79 stand rejected under 35 U.S.C. § 103(a) as being obvious over by U.S. Patent No. 5,719,197 to Kanios et al. ("Kanios"). Applicant respectfully traverses.

Applicant submits that the Office Action has not made out a *prima facie* case of obviousness. The Applicant's claims are directed to buccal spray compositions and methods capable of transmucosal absorption of an active compound through the oral mucosa to the systemic circulatory system. The only reference in Kanios to any dosage form being applied to the oral mucosa is in the background of the art referring to a local anesthesia (Kanios, col. 1, lines 46-55) and at col. 6, lines 59-61, again referring only to a local anesthesia composition. Moreover, in both instances, Kanios fails to disclose any buccal spray composition.

The Office Action acknowledges that "Kanios does not exemplify a buccal spray-formulation." The Office Action continues, however, that forming a buccal spray containing an active and a solvent "would be a logical extension" of the disclosure of Kanios. Office Action at 3. Applicant respectfully submits that this "extension" from the disclosure of Kanios is based on an impermissible use of hindsight and is not based on any fair reading of the prior art.

The Office Action also acknowledges that "Kanios is essentially about topical application by a flexible or adhesive composition." The Applicant's claims, in contrast, recite a buccal spray composition, which is not disclosed or even suggested based on any

fair reading of Kanios. The Office Action, however, points to columns 9 and 10 of Kanios and alleges:

> Kanios is teaching other forms of compositions including liquid sprays. Applicants attention is drawn to column 9, lines 19-27, where Kanios recites "For example, in ONE embodiment, the anesthetic agents are dissolved in a solvent .... and then added to an adhesive. In ANOTHER embodiment, the resulting mixture is in cream, gel..., spray solution or other non-finite composition...". Also in column 10, lines 57-65 Kanios discloses that ".... when a non-finite carrier such as an ointment, gel, lotion ... or spray-solution is used".

Applicant respectfully disagrees that these passages of Kanios can be said to disclose or suggest the claimed buccal spray. The cited passages of Kanios actually read as follows (emphasis added):

> The composition in question can then be applied to a flexible backing or a combination of backings which will serve to define the size and shape of a single dosage of the composition. Such backing may be a three dimensional material such as paper, a non-woven fabric or a natural or synthetic polymer substance. Methods of coating backings are well-known in the art and include techniques involving Mayer rod, gravure, and knife-over roll. Further processing of backings may involve the use of converting equipment for die cutting.
>
> The finished dosage form will be substantially occlusive to water permeation in in vivo.
>
> For example, in one embodiment, the anesthetic agents are dissolved in a solvent, preferably a polyhydric alcohol, and then the resulting mixture is added to an adhesive prior to being placed onto the flexible form or backing. In another embodiment, the resulting mixture is an cream gel, emulsion lotion, salve, plaster, paste, ointment, spray-solution or other "non-finite" composition. The final form which the composition of the invention will be applied depends upon the anatomical site of application and ease of access.

The finished dosage form of Kanios is made of an active agent and either a finite or non-finite pharmaceutical carrier (i.e., the "resulting mixture" in col. 9, lines 21 and 23). There

is no disclosure in Kanios that the "resulting mixture" is administered directly to the oral mucosa in any form, much less as a buccal spray. According to Kanios, the composition in question is made into a "finished dosage form" by applying a flexible backing which further defines the size and shape of the finished dosage form, which is, among other things, occlusive to water permeation in vivo. In contrast to the present invention, Kanios never discloses that its finished dosage form is a spray, much less a buccal spray capable of providing a systemic effect.

At column 10, lines 57-65 (cited in the Office Action), Kanios refers to appropriate "sizes" of the composition and the amount of agent per "surface area" of the finished dosage form. That this paragraph of Kanios also refers to mg/ml concentrations for anesthetic agents is in no way a disclosure of a spray final dosage form. The intermediate resulting mixture of Kanios will have a concentration of active when added to an adhesive, backed by a flexible backing, or otherwise made into the finite finished dosage form of Kanios. Therefore, simply because an anesthetic agent concentration is disclosed, does not disclose or suggest a finished dosage form suitable for spraying on the oral mucosa. Such a spray dosage form is never contemplated or taught by the portion of Kanios cited in the Office Action, or in any other portion of the Kanios disclosure.

To establish *prima facie* obviousness, the prior art reference(s) must teach or suggest all of the claim limitations. In re Royka, 490 F.2d 981, 180 U.S.P.Q. 580 (C.C.P.A. 1974). Because Kanios does not disclose or suggest any buccal spray, Kanios cannot render any of Applicant's composition claims obvious for at least this reason. Moreover, Applicant's method claims 37-38 and 60-61 require "spraying the oral mucosa" of an animal with the claimed buccal spray composition. Kanios does not contain one iota of any disclosure or suggestion of spraying its resulting pharmaceutical carrier/active mixture or its finished, finite dosage forms, on the oral mucosa.

In addition, the amended claims require that the composition is capable of providing transmucosal absorption to the systemic circulatory system. This is not a mere intended use, but instead a required property -- i.e., the recited buccal spray composition is

"capable of" absorption systemically through the oral mucosa. Kanios nowhere discloses this property, which is required by each of Applicant's claims, in any of the topical, locally acting, dosage forms disclosed therein. Kanios does not even remotely disclose or suggest the claimed property in any buccal spray. It is respectfully submitted that the Office Action employs a reconstruction using portions of the Kanios disclosure (such as Kanios' Background of the Art) out of context and improper hindsight reasoning. In re Fine, 837 F.2d 1071, 1075 (Fed. Cir. 1988).

There is absolutely no disclosure or suggestion in Kanios of a composition that is capable of providing transmucosal absorption of the active compound through the oral mucosa of a mammal to the systemic circulatory system, as presently claimed. Kanios merely discloses local anesthetic agent compositions that are applied topically and then have a local effect. While Kanios refers to a shotgun list of pharmaceutical agents, there is, however, no disclosure or suggestion of a buccal spray composition capable of providing transmucosal absorption of an active compound to the systemic circulatory system, as presently claimed.

The systemic circulation claim element is a required property of Applicant's composition claims and cannot be overlooked as mere "intended use." Office Action at 6. Moreover, Applicant's method claims expressly recite spraying the oral mucosa and providing the active to the systemic circulatory system. Kanios' topical, locally-acting final dosage forms cannot be used in such method and Kanios simply never discloses or suggests a method of administering an active compound to the systemic circulatory system via spraying to the oral mucosa. For each of the above reasons, Applicant submits that the § 103 rejection over Kanios is improper and should be withdrawn.

Claims 27-29, 31-32, 34, 38, 54-55, 57, and 61 stand rejected under 35 U.S.C. § 103(a) as being obvious over Kanios and further in view of U.S. Patent No. 5,364,616 to Singer et al. ("Singer"). Applicant respectfully traverses.

Singer refers to methods for preventing or treating gingivitis (inflammation of the gums) or periodontitis (inflammation of the tissue that support the teeth) comprising topically administering to gingival tissue of the oral cavity a composition comprising a safe and effective amount of a selective histamine-2 receptor antagonist compound (See, e.g., Singer, col. 2, lines 32-37 and col. 1, lines 16-17 and 26-27).

The Examiner cites Singer for allegedly disclosing concentration ranges and examples of flavoring agents. The mere disclosure of concentration ranges and examples of flavoring agents does not overcome the deficiencies in Kanios, i.e., that unlike the claimed invention, Kanios' finished dosage forms are not buccal sprays, much less buccal sprays capable of systemic active ingredient effect.

To treat gingivitis or peridontitis one would want the composition to remain in the oral cavity and not to be delivered to the systemic circulatory system. Indeed, Singer states that the disclosed "topical, oral carrier" denotes a composition "which is administered topically to the oral cavity, held therein for a period of time, and then is largely expectorated rather than being swallowed" (See, e.g., Singer, column 15, lines 26-30). There is no disclosure or suggestion in Singer of a buccal spray capable of transmucosal absorption to provide an active compound to the systemic circulatory system, as presently claimed.

The proper inquiry for obviousness is whether the references disclose each and every feature of the claim (See, e.g., MPEP, 1242) and whether the references suggest the invention and provide one of ordinary skill in the art with a reasonable expectation of success. In re Vaeck, 947 F.2d 488, 20 U.S.P.Q. 2d 1438 (Fed. Cir. 1991); In re O'Farrell 853 F.2d 894, 7 U.S.P.Q. 2d 1673 (Fed. Cir. 1988). Neither Kanios nor Singer render the present claims obvious since neither of the references, either alone or in combination, (a) discloses each and every feature of the invention and (b) provides a reasonable expectation of success. There is no disclosure or suggestion in either Kanios or Singer of a buccal spray composition capable of being applied to the oral mucosa to provide an active compound to the systemic circulatory system or any disclosure on how to

get a systemic effect via a buccal spray composition or method. Furthermore, neither Kanios or Singer, either individually or in combination, provides the required reasonable expectation that a composition applied to the oral mucosa could provide an active compound to the systemic circulatory system, as presently claimed.

For the above reasons, Applicant respectfully requests that the rejections under 35 U.S.C. § 103(a) be reconsidered and withdrawn.

In view of the above, Applicant believes the pending application is in condition for allowance. If the Examiner should believe that anything further may be required to place this application in even better form for allowance, she is cordially invited to telephone the Applicant's undersigned representative.

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Respectfully submitted,

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